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Guidance for the Reregistration of Pesticide Products Containing Formetanate Hydrochloride (097301) as the Active Ingredient

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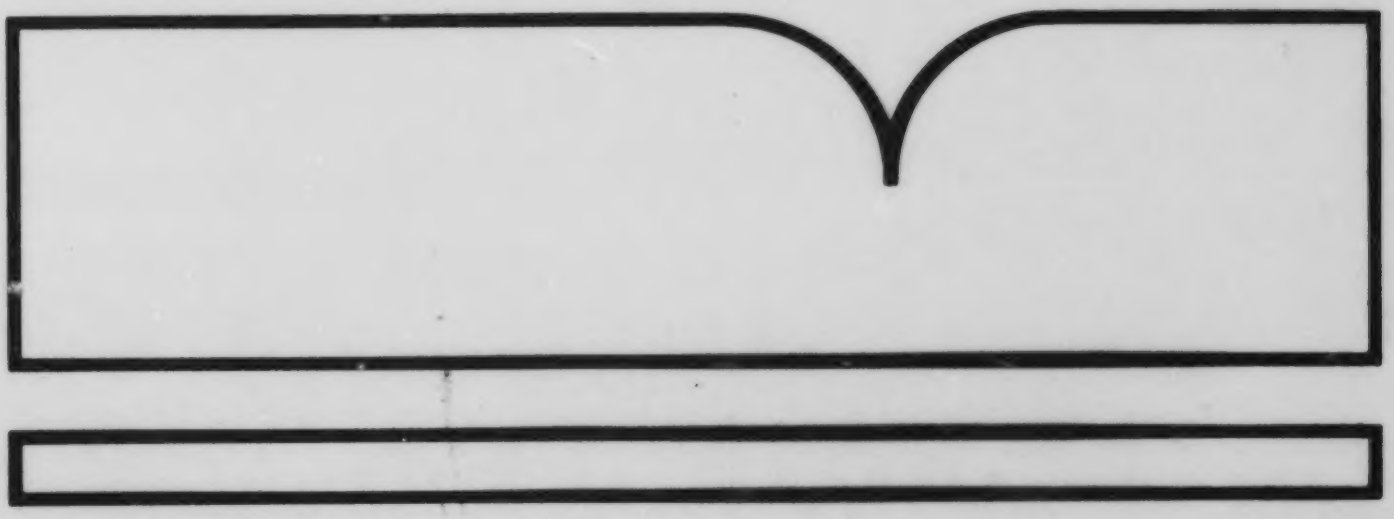

U.S. Department of Commerce
National Technical Information Service
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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING FORMETANATE HYDROCHLORIDE (097301) AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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16. Abstract (Limit: 200 words)

This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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Note: Appendices IV-1, IV-4 and IV-6 are not germane to this document and are not included.

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic

suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time-frames outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this Guidance Document which do not relate to compliance with the §3(c)(1)(D) provisions and to supplement the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

A. Introduction

This guidance document describes the Agency's regulatory position on registered manufacturing-use products (MPs) containing the miticide/insecticide formetanate hydrochloride (formetanate HCl). The position is based on an evaluation of all accepted uses of pesticide products, under section 3 and 24(c) of the FIFRA, with formetanate HCl as the pesticide active ingredient. Other considerations include the known chemical and toxicological characteristics of this pesticide chemical and the established tolerances for residues in or on food and feed commodities. From these considerations the Agency sets forth the data and labeling requirements that must be met by registrants and applicants of formetanate HCl products in order for the products to be reregistered or registered under this document. Only those registration requirements for current and future substantially similar MPs are addressed here. Future MPs that differ appreciably from those described in this document may require that amendments be made to this document to reflect the differences.

B. Description of Chemical And Use Profile

Formetanate HCl is the American National Standards Institute (ANSI) acceptable common name for m-[[(Dimethylamino)methylene] amino]phenyl methylcarbamate hydrochloride. The compound is listed in the 8th Collective Index of the Chemical Abstracts Service of the American Chemical Society as methylcarbamic acid ester with N'-(m-hydroxy= phenyl)-N,N-dimethylformamidine monohydrochloride. The 9th Collective Index chemical name is: N,N-dimethyl-N'-[3-[[(methylamino) carbonyl]oxy]phenyl] methanimidamide monohydrochloride. Other names and code designations are: Schering A.G. 36056, ENT-27566, SN-36056 and Dicarzol (the West German name for Carzol SP). The current Chemical Abstract Service (CAS) registry number for formetanate HCl is 23422-53-9 and the EPA Shaughnessy number is 097301.

Formetanate HCl is a white crystalline solid with a faint odor. The empirical formula is $C_{11}H_{15}N_3O_2$.HCl. The molecular weight is 257.8. Formetanate HCl is more than 50% soluble in water but only slightly soluble in most organic solvents.

In addition to the federal registration, Carzol® SP is registered for intra-state use in Arizona, California, Oregon, Texas, Washington and Florida.

This pesticide is not produced domestically and is imported into the U.S. only from West Germany, where it is manufactured by the Schering A.G. Chemical Company. In the United States, the sole importer and distributor of the chemical is NOR-AM Agricultural Products, Inc. of Naperville, IL, a subsidiary of Schering A.G. Chemical Company. Formetanate HCl is formulated and registered as a 92% watersoluble powder for both the MP and EP registrations. The MP is registered for the use of reformulating into an EP, and this is registered for use to control mites, thrips and other insect pests on citrus, pome and stone fruit crops, and alfalfa grown-for-seed.

C. Regulatory Position

Based on a review and evaluation of all available data and other relevant information on formetanate HCl, the Agency has made the following determinations:

1. Available data do not show that any of the criteria listed in Section 162.11 (a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of formetanate HCl listed in this Guidance Document. However, gaps in the data base preclude the completion of the Agency's risk assessment.

2. Although the Agency is unable to complete a full tolerance reassessment because of certain residue chemistry and toxicology data gaps, the Agency concludes that no change in present tolerances are indicated at this time. A valid acceptable daily intake level (ADI) cannot be calculated at this time because the toxicology studies needed to calculate the ADI were conducted by IBT and have been invalidated. When new studies are submitted an ADI will be calculated and the theoretical maximum residue contribution (TMRC) will be recalculated.

3. The Agency has not established a reentry interval for field workers entering treated fields. However, the state of California, Department of Food and Agriculture, has a 24-hour reentry interval for formetanate HCl and all other pesticides in Toxicity Category I. For this Guidance Document the Agency has now adopted this 24-hour interval on orchard crops. The registrant can either accept this or submit data on which to base a different reentry level. The Agency reserves the right to revise this reentry interval and to impose additional label requirements after receipt and review of the data required in Table A and Table B of this Guidance Document.

4. Manufacturing-use pesticide products containing formetanate HCl as a sole active pesticide ingredient may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Guidance Document.

5. Registrants must provide or agree to develop additional data, as specified in the tables, in order to maintain existing registrations or to obtain new registrations of substantially similar MPs.

D. Regulatory Rationale

The Agency has determined that it should continue to allow the registration of formetanate HCl after considering the following:

1. Adequate studies are available to assess the acute toxicological effects of formetanate HCl to humans. Formetanate HCl is assigned Toxicity Category I on the basis of acute oral and eye effects. The eye irritation study triggers one of the criteria [40 CFR 162.11(c)(1)(ii)] used to classify pesticides. However, the classification regulations also state [40 CFR 162.11(c)(3)] that if the criteria are met, labeling precautions and directions must be evaluated to determine if the potential hazard will be mitigated. The use requirement to wear goggles, face shield or safety glasses as required by this guidance document is adequate to protect a person from eye injury if exposed to this chemical. Therefore, formetanate HCl is not being classified as a Restricted Use Pesticide. The above precautionary statement along with other human hazard precaution statements associated with Toxicity Category I labeling [40 CFR 162.10(h)(2)(i)] should minimize the acute hazards associated with these routes of exposure.

2. Formetanate HCl may potentially yield both aromatic and alkyl amines. These amines may be converted to reactive electrophilic species (such as nitroso species) with possible oncogenic effects. The Agency will assess the need for further characterization of the postulated electrophilic species when the results of the required chronic feeding and oncogenic studies are submitted and reviewed. No other human toxicological hazards of concern to the Agency have been identified. It is noted however, that a number of multiple dose toxicology studies submitted in support of this pesticide were conducted by Industrial Bio-Test Laboratories (IBT) and have been determined to be invalid.

3. The tolerance reassessment and TMRC/ADI ratio must be completed. However, based on residue chemistry and toxicological considerations, there is no evidence to suggest that the current tolerances are likely to expose the public to unreasonable adverse effects.

4. There is no record of any incident involving formetanate HCl having been reported to the Pesticide Incident Monitoring System (PIMS).

5. Available data are insufficient to fully assess the environmental fate of formetanate HCl. Formetanate HCl appears to leach in soil and, therefore, has a potential for contamination of groundwater. The additional studies requested in this Guidance Document should allow us to improve our assessment of the environmental fate of formetanate HCl. Upon receipt and analysis of these data the Agency may require additional studies such as groundwater monitoring.

6. Based on acceptable ecological effects studies, formetanate HCl is characterized as highly toxic to birds. It is slightly toxic to warmwater fish and moderately toxic to estuarine and marine organisms. It is moderately toxic to honey bees with direct contact spray, but it has very low toxicity to bees when they are exposed to residues on plants. Label precautions required by this Guidance Document should reduce the hazard to wildlife. Once data gaps are filled, additional labeling precautions may be required.

7. Under FIFRA, the Agency cannot cancel or withhold registration simply because data are missing or are inadequate (see Sections 3(c)(2)(B) and 3(c)(7) of the FIFRA). Rather, issuance of this Guidance Document provides a mechanism for identifying data needs. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registration(s) of formetanate HCl.

E. Criteria for Products Subject to the Guidance Document

This Guidance Document covers products that contain formetanate HCl as a pesticide active ingredient, and the chart in the Introduction describes the extent to which such products are subject to this Document. Applicants for registration or reregistration of such products must comply with all terms and conditions described herein. This includes making a commitment to fill data gaps on a schedule specified by the Agency. Also, applicants for reregistration must follow the instructions contained in the Guidance Document and complete and submit the appropriate forms within the specified times. End-use products must be in compliance with the label changes specified in this Document.

F. Acceptable Ranges and Limits

1. Product Composition Standards

To be fully covered under this Guidance Document, manufacturing-use products must contain formetanate HCl as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider for registration any MP whose acute toxicity category (I, II, III or IV) is supported by adequate acute toxicity data and labeling, including appropriate precautionary statements.

3. Use Patterns

To be registered under this Guidance Document, MP's may be labeled for formulation only into end-use products for: 1) terrestrial, nondomestic food crop uses on citrus (oranges, lemons, tangerines, tangelos, limes and grapefruit), pome fruits (apples and pears), stone fruits (peaches, nectarines, plums, and prunes) and alfalfa grown-for-seed.

G. Required Labeling

All manufacturing-use products and end-use products containing formetanate HCl must bear appropriate labeling as specified in 40 CFR 162.10.

1. Label Requirements for Manufacturing-Use Products

a. Ingredient Statements

The ingredient statement for MP's must list the active ingredient as formetanate hydrochloride (N,N-dimethyl-N'-[3-[[(methylamino)carbonyl]oxy]phenyl]methanimidamide monohydrochloride)..... _____ % or formetanate hydrochloride (m-[[(Dimethylamino)methylene]amino]phenyl methylcarbamate hydrochloride).... _____ %.

b. Use Pattern Statement

1. All MPs must state that they are intended only for formulation into end-use products for any of the use patterns listed above (F-3). A limiting factor will be the data that supports these use patterns. No use may be included in the labeling where the registrant fails to agree to comply with the data requirements in either Table A or Table B for that use pattern.

c. Precautionary Statements

Labels for all MP products containing formetanate HCl must bear statements reflecting the acute human toxicity of the compound. The following hazard statements must appear on MP labels.

1. Statement for human hazards.

"HAZARDS TO HUMANS AND DOMESTIC ANIMALS"

"DANGER. Fatal if swallowed. Do not breathe spray mist. Can cause irreversible eye damage. May cause skin sensitization. Do not get in eyes, on skin or on clothing. Wear goggles, face shield or safety glasses. Wear a pesticide respirator approved jointly by the Mining Enforcement and Safety Administration (formerly U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse."

2. Statement of environmental hazards.

"ENVIRONMENTAL HAZARDS"

"This pesticide is toxic to wildlife. Do not discharge into lakes, streams, ponds or public water except in accordance with an NPDES permit. For further guidance, contact the nearest EPA Regional Office."

When the data to be submitted under this Guidance Document has been reviewed, the Agency may impose additional label requirements.

2. Label Requirements for End-Use Products

a. Ingredient Statement

1. The ingredient statement for end-use products (EP's) must list the active ingredient as formetanate hydrochloride (N,N-dimethyl-N'-[3-[[(methylamino)carbonyl]=oxy]phenyl]methanimidamide monohydrochloride)... %
or formetanate hydrochloride (m-[[(Dimethylamino)methylene]amino]phenyl methylcarbamate hydrochloride ...____ %.

b. Use Pattern Statements

1. A reentry statement must be added to the labeling and read as follows: "Do not enter treated areas for 24 hours unless protective clothing is worn."

2. The label must be amended to restrict the use on nectarines and peaches to West Coast states only or additional data on residues from other geographic areas must be submitted.

c. Precautionary Statements

Labels for all EP products containing formetanate HCl must bear statements reflecting the acute human toxicity of the compound. The following hazard statements must appear on EP labels:

1. Statement for human hazard.

"HAZARDS TO HUMANS AND DOMESTIC ANIMALS"

"DANGER. Fatal if swallowed. Do not breathe spray mist. Can cause irreversible eye damage. May cause skin sensitization. Do not get in eyes, on skin or on clothing. Wear goggles, face shield or safety glasses. Wear a pesticide respirator approved jointly by the Mining Enforcement and

Safety Administration (formerly U.S. Bureau of Mines) and by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II. Wash thoroughly with soap and water after handling and before eating or smoking. Remove contaminated clothing and wash before reuse."

2. Statement for environmental hazard.

"ENVIRONMENTAL HAZARDS"

"This pesticide is toxic to wildlife. Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes. Cover or incorporate spills. This product is toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product if bees are visiting the treatment area.

H. Tolerance Reassessment

Based on the established tolerances published in 40 CFR 180.276, the theoretical maximum residue contribution (TMRC) from formetanate HCl residues to the human diet is calculated to be 0.41 mg/day from a 1.5 kg food diet for a 60 kg person.

The Agency considers the current values for the acceptable daily intake (ADI) of 0.025 mg/kg/day and the maximum permissible intake (MPI) of 1.5 mg/day/60 kg (MPI = ADI x 60 kg) as provisional. This is because a number of multiple dose toxicity studies submitted to establish the ADI/MPI were conducted by IBT and have been determined to be invalid. Another reassessment and recalculation of the ADI/MPI will be made when studies required to fill the toxicology data gaps have been submitted and validated.

If different values are determined for the ADI and MPI then the ratio between the MPI and TMRC will be reviewed. It is possible at that time, that the established tolerances may be affected.

The Agency notes that formetanate HCl is very unstable in rat diets. The protocol of any feeding study should specify a daily dietary preparation. In addition, we suggest that with the protocol of any formetanate HCl chronic or subchronic study, adequate data or citations should be included to show that the determination of cholinesterase inhibition, stipulated by the protocol, is optimal for carbamates.

A petition for a tolerance for residues in or on alfalfa forage and alfalfa hay must be submitted to support the alfalfa grown-for-seed use or the use must be deleted from the label. No residue data are available. A registration was granted when this use was regarded as a non-food use. The Agency now considers the use on alfalfa grown-for-seed to be a food use. Alfalfa sprouts are used as a human food item. Also, there is a likelihood that the label restrictions will not be followed, with the possibility of subsequent cuttings being fed to livestock and poultry.

A new petition for a food additive tolerance for residues in or on dried apple pomace must be submitted. A food additive petition for dried apple pomace had been previously submitted but was subsequently withdrawn.

If there is evidence to show a transfer of pesticide residues to meat, poultry, milk or eggs, petitions for tolerances for the residues in these commodities must also be submitted.

The U.S. and Canada have the same tolerances for residues in citrus, apples and pears. Tolerances for peaches and plums differ between the U.S. and Canada. In the U.S., the residue limit for peaches is 5 ppm and for plums is 2 ppm, while the Canadian residue limits are 3 ppm and 0.5 ppm, respectively. At present, lowering the U.S. tolerances to meet the Canadian level

is not desirable because the registered pesticide use rate and the pre-harvest interval would be affected. All remaining U.S. and Canadian tolerances are in agreement. There are no listing for this pesticide by Mexico or in the Codex Alimentarius.

:097301

FORMETANATE HYDROCHLORIDE*

TYPE PESTICIDE: Insecticide, Acaricide

FORMULATIONS: Tech (92%); SC/S (92%)

GENERAL WARNINGS AND LIMITATIONS: Formetanate hydrochloride is not stable in alkaline water. Do not prepare more spray than will be used within 4 hours after preparation.
Bee Caution:
This product is toxic to bees and should not be applied when bees are actively visiting the area.
Agricultural Crop Tolerances:
Limes - 4 ppm

Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
AGRICULTURAL CROPS		
General Warnings and Limitations: Do not allow livestock to graze cover crops in treated orchards. Unless otherwise indicated, apply when pest first appears and repeat as needed. Unless otherwise indicated, the dosage and gallonage used on fruit trees is dependent upon the size of the trees.		
/23001BA Alfalfa (seed crop)		N.F. Use limited to CA, ID, NV, OR, and WA. For use on pure stands of alfalfa to be harvested for seed. Do not apply following onset of bloom in ID, NV, OR, and WA. Do not graze livestock in treated fields. Do not use treated crops or crop residues for livestock feed or forage. Treated fields must be cleared following harvest by burning or discing.
:QAQAFA Consperse stink bug	0.92 lb/A (92% SC/S)	Use limited to CA. Foliar application. For knockdown of heavy nymphal populations. A lygus bug control program will control the consperse stink bug. Apply by aircraft in a minimum of 5 gallons per acre or by ground equipment in a minimum of 20 gallons of water per acre.

*m-[[(dimethylamino)methylene]amino]phenyl methylcarbamate hydrochloride
Carzol SP

FORMETANATE HYDROCHLORIDE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Alfalfa (seed crop) (continued)		
IQAMARA	Lygus bugs	0.46-0.92 lb/A (92% SC/S)	Foliar application. Apply when lygus bugs reach damaging numbers and repeat as needed. Consult State Agricultural Experiment Station or Agricultural Extension Service for proper timing information.
ILAVBEA	Twospotted spider mite	0.46-0.92 lb/A (92% SC/S)	Foliar application. Apply by aircraft in a minimum of 10 gallons of water per acre or by ground equipment in a minimum of 20 gallons of water per acre.
/04001AA	Apple		3 ppm 7 day preharvest interval through 3.68 pounds per acre for foliar application. Do not apply more than 3.68 pounds per acre in the growing season.
ILAVASA ILAVBEA ITAPABA	European red mite Twospotted spider mite Tentiform leafminers	0.23-0.46 lb/100 gal [400-900 gal/A] (92% SC/S)	Foliar application. Dosage used depends on the size of the trees and the severity of the infestation.
ITAPABA	Tentiform leafminers	0.92-3.68 lb/A (92% SC/S)	Foliar application. Apply as a concentrate spray in a minimum of 50 gallons of water per acre.
IRAFBAA	White apple leafhopper	0.115-0.23 lb/100 gal [400 gal/A] or 0.46-0.92 lb/A (92% SC/S)	Foliar application. Per acre rates are to be applied as a concentrate spray application in a minimum of 50 gallons of water per acre.

FORMETANATE HYDROCHLORIDE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/02002AA	Grapefruit		4 ppm 7 day preharvest interval through 4.6 pounds per acre for foliar application. Allow 30 days between applications. Do not apply more than 4.6 pounds per acre in a 12 month period.
ILAJBCA	Citrus rust mite	0.0575-0.115 lb/100 gal [500-1500 gal/A] (92% SC/S)	Use limited to FL. Foliar application.
		0.115-0.23 lb/100 gal [500 gal/A] (92% SC/S)	Use limited to TX. Foliar application.
IMOAAAA	Thrips	0.46 lb/ 100 gal [100-300 gal/A] or 0.46-1.38 lb/A (92% SC/S)	Use limited to AZ and CA. Foliar application. Apply per acre rate by aircraft in a minimum of 10 gallons of water per acre.
/02004AA /02006AA /02008AA	Lemon Orange Tangerine		4 ppm 7 day preharverst interval through 4.6 pounds per acre for foliar application. Allow 30 days between applications. Do not apply more than 4.6 pounds per acre in a 12 month period.
ILAVARA	Citrus red mite	0.46 lb/ 100 gal [700-1,000 gal/A] (92% SC/S)	Use limited to AZ and CA. Foliar application.
ILASBCA	Citrus rust mite	0.0575-0.115 lb/100 gal [500-1,500 gal/A] (92% SC/S)	Use limited to FL. Foliar application.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Lemon cluster (continued)		
		0.115-0.23 lb/100 gal [500 gal/A] (92% SC/S)	Use limited to TX. Foliar application.
IMOAAAA	Thrips	0.46 lb/ 100 gal [100-300 gal/A] or 0.46-1.38 lb/A (92% SC/S)	Use limited to AZ and CA. Foliar application. Apply per acre rate by aircraft in a minimum of 10 gallons of water per acre.
/05003AA	Nectarine		4 ppm 14 day preharvest interval through 1.84 pounds per acre for foliar application. Do not apply more than 3.68 pounds per acre in a growing season.
ILAVASA ILAVAYA ILAVBEA	European red mite McDaniel spider mite Twospotted spider mite	0.23 lb/ 100 gal [400-500 gal/A] or 0.92-1.15 lb/A (92% SC/S)	Foliar application. Apply per acre rate as a concentrate spray in a minimum of 50 gallons of water per acre.
IMOAAAA	Thrips	0.23-0.345 lb/100 gal [400-500 gal/A] or 0.92-1.84 lb/A (92% SC/S)	Foliar application. Apply when thrips infest blossoms through petal fall. Apply at night or when bees are not working in blooms. Apply per acre rate as a concentrate or aerial application.
	Orange	See Lemon cluster.	

FORMETANATE HYDROCHLORIDE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
05004AA	Peach		5 ppm 21 day preharvest interval through 1.15 pounds per acre for foliar application. Do not apply more than 2.3 pounds per acre in a growing season.
ILAVASA IQAMARA ILAVAYA IQAQABA ILAVBEA	European red mite Lygus bugs McDaniel spider mite Stink bugs Twospotted spider mite	0.23 lb/100 gal [400-500 gal/A] or 0.92-1.15 lb/A (92% SC/S)	Foliar application. Apply per acre rate as a concentrate spray in a minimum of 50 gallons of water per acre.
04003AA	Pear		3 ppm 7 day preharvest interval through 3.68 pounds per acre for foliar application. Do not apply more than 3.68 pounds per acre in a growing season.
ILAVASA ILAVBEA	European red mite Twospotted spider mite	0.23-0.46 lb/100 gal [400-800 gal/A] (92% SC/S)	Foliar application. Dosage used depends on the size of the trees and the severity of the infestation.
ILAJAOA	Pear rust mite	0.23 lb/100 gal [400-800 gal/A] (92% SC/S)	Foliar application. Apply from postbloom to harvest beginning application at first sign of mite infestation.
05005AA 05006AA	Plum Prunes		2 ppm (plums, fresh prunes) 7 day preharvest interval through 1.38 pounds per acre for foliar application. Do not apply more than 2.76 pounds per acre in a growing season.
ILAVASA ILABAYA ILAVBEA	European red mite McDaniel spider mite Twospotted spider mite	0.23 lb/100 gal [400-600 gal/A] or 0.92-1.38 lb/A (92% SC/S)	Use limited to the West Coast. Foliar application. Apply per acre rate as a concentrate spray in a minimum of 50 gallons of water per acre.

FORMETANATE HYDROCHLORIDE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/02007AA	Tangelo		4 ppm (tangerines) 7 day preharvest interval through 1.38 pounds per acre for foliar application. Allow 30 days between applications. Do not apply more than 4.6 pounds per acre in a 12 month period.
IMOAAAA	Thrips	0.46 lb/ 100 gal [100-300 gal/A] or 0.46-1.38 lb/A (92% SC/S)	Use limited to AZ and CA. Foliar application. Apply per acre rate as an aerial application in a minimum of 10 gallons of water per acre.
	Tangerine	See Lemon cluster.	

AERIAL, MOTHPROOFING AND TANK MIX APPLICATIONS

9001500 AAAAAAA	Aerial Application		
	--	Refer to AGRICULTURAL CROPS	Alfalfa, Grapefruit, Lemon, Orange, Tangelo, Tangerine

FORMETANATE HYDROCHLORIDE

Listing of Registered Pesticide Products by Formulation

92% technical chemical
formetanate hydrochloride (097301)
002139-00114

92% soluble concentrate/solid
formetanate hydrochloride (097301)
002139-00099

State Label Registrations

AZ Reg. No.
002139-04325

CA Reg. No.
002139-04324

FL Reg. No.
002139-04326

OR Reg. No.
002139-04322

TX Reg. No.
002139-04327

WA Reg. No.
002139-04359

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data [1/] Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCL

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Partial	GS0091006*	Yes[3]
61-2 - Statement of Composition	TGAI	Partial	GS0091006* 00077659	Yes[3]
61-3 - Discussion of Formation of Ingredients	TGAI	No	-	Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	Partial	GS0091006*	Yes[3]
62-2 - Certification of Limits	TGAI	Partial	GS0091006*	Yes[4]
62-3 - Analytical Methods for Enforcement Limits	TGAI	Yes	GS0091011	No

* Data submitted by Nor-Am Agricultural Products, Inc. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry (continued)				
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	GS0091005	No
63-3 - Physical State	TGAI	Yes	GS0091005	No
63-4 - Odor	TGAI	Yes	GS0091005	No
63-5 - Melting Point	TGAI	Yes	GS0091005	No
63-6 - Boiling Point	TGAI	No	-	No[5]
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No	-	Yes

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirement	Composition [1]	Does EPA Have Data To Satisty This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	TGAI OR PAI	Yes	GS0091005	No
63- 9 - Vapor Pressure	PAI	Yes	GS0091005	No
63-10 - Dissociation constant	PAI	No	-	Yes
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes
63-12 - pH	TGAI	No	-	Yes
63-13 - Stability	TGAI	Yes	GS0091005	No
Other Requirements:				
64- 1 - Submittal of samples	TGAI	No	-	No[6]

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than March, 1984.
3/ Updated information must be supplied on identity and quantity of impurities and inerts.
4/ Explanation required from registrant on how certified limits are maintained.
5/ Not applicable for a solid material.
6/ Agency will request samples when the need arises.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirements	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partial	00077703*;GS0091012*	Yes[3] 10
- Livestock	PAIRA and plant metabolites	Partial	GS0091009*	Yes[4]
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Yes	GS0091010;GS0091017; GS0091018	No[10]
- Animal residues	TGAI and metabolites	No	-	Yes[5]
171-4 - Storage Stability Data	PAIRA	Yes	GS0091011;GS0091012*; GS0091013*;GS0091014*	No[10]
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Citrus group				
Grapefruit	TEP	Yes	GS0091011;GS0091012* GS0091013*	No[10]
Lemons	TEP	Yes	GS0091011;GS0091012*; GS0091013*	No[10]
Limes	TEP	Yes	GS0091011;GS0091012*; GS0091013*	No[10]
Oranges	TEP	Yes	GS0091011;GS0091012*; GS0091013*	No[10]
Tangerines	TEP	Yes	GS0091011;GS0091012*; GS0091013*	No[10]

* Data submitted by Nor-Am Agricultural Products, Inc. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCL

Data Requirements	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
171-4 Magnitude of the Residue (continued)				
Pome Group				
Apples	TEP	Yes	GS0091011;GS0091012*; GS0091015*;GS0091022*	No[8,10]
Pears	TEP	Yes	do	No[10]
Stone Group				
Plums	TEP	Yes	GS0091011;GS0091014*	No[10]
Prunes	TEP	Yes	do	No[10]
Nectarines	TEP	Partial	do	Yes[6 10]
Peaches	TEP	Partial	do	Yes[6 10]
Alfalfa, forage	TEP	No	-	Yes[7]
Alfalfa, hay	TEP	No	-	Yes[7]
Residues in Processed Commodities				
Citrus Molasses	TEP	Yes	GS0091016*;GS0091012*	No[10]
Dried Apple Pomace	TEP	Partial	GS0091015*;GS0091022*	Yes[8]
Dried Prunes	TEP	Yes	GS0091021*	No

* Data submitted by Nor-Am Agricultural Products, Inc. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirements	Composition[1]	Does EPA Have Data To Satisty This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
171-4 - Magnitude of the Residues in Food-producing animals				
Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	No	-	Yes[9]

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

§158.125 Residue Chemistry
(continued)

1/ Composition: TGAI = Technical grade of active ingredient; PAIRA = Pure active ingredient, radio labeled; TEP = Typical end-use product.

2/ Data on alfalfa, forage, alfalfa, hay and analytical methods must be submitted no later than September, 1984. Data from other geographic areas for peaches and nectarines must be submitted no later than September, 1984. All other residue chemistry data must be submitted no later than September, 1986.

3/ A radio tracer metabolism study on alfalfa or a similar crop must be submitted if a tolerance is proposed for alfalfa.

4/ Data on the metabolism of formetanate HCl in a large ruminant animal and in poultry are needed.

5/ If feeding studies indicate a transfer of residues to animal products, then analytical methods must be developed to determine these residues.

6/ Current data are only from West Coast states. Additional data must be submitted from other representative geographic areas or the EP label must be amended to limit the use to West Coast states.

7/ A petition for a tolerance for residues in or on alfalfa, forage, and alfalfa, hay must be submitted to support the alfalfa grown-for-seed use or the use must be deleted from the EP label. (See 2 above)

8/ A petition must be submitted for a food additive tolerance for residues in or on dried apple pomace.

9/ Feeding studies are required to determine if there is a transfer of pesticide residues to meat, milk, eggs, and poultry when livestock are fed with fruit pomace, citrus molasses and alfalfa products containing formetanate HCl. It residues are found, then appropriate tolerances must be requested.

10/ All data citations are required to support the data requirements.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.130 Environmental Fate					
Degradation Studies-Lab:					
161-1 - Hydrolysis	TGAI or PAIRA	A	No	-	Yes[4]
Photodegradation:					
161-2 - In water	TGAI or PAIRA	A	No	-	Yes[5]
161-3 - On Soil	TGAI or PAIRA	A	No	-	Yes[5]
161-4 - In Air	TGAI or PAIRA	A	No	-	No[6]
Metabolism Studies Lab:					
162-1 - Aerobic Soil	TGAI or PAIRA	A	No	-	Yes[7]
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No	-	Yes
162-3 - Anaerobic Aquatic	TGAI or PAIRA	-	Not Applicable	-	No[8]
162-4 - Aerobic Aquatic	TGAI or PAIRA	-	Not Applicable	-	No[8]
Mobility Studies:					
163-1 - Leaching and Absorption/ Desorption	TGAI or PAIRA	A	No	-	Yes[9]
163-2 - Volatility (Lab)	TEP	A	No	-	No[6]
163-3 - Volatility (Field)	TEP	A	No	-	No[6]

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation 7	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.130 Environmental Fate (continued)					
Dissipation Studies - Field:					
164-1 - Soil	TEP	A	Partial	00077734*;00077735* 00077709*;00077731*; 00077732*;00077733*; 00077730*	Yes 10/
164-2 - Aquatic (Sediment)	TEP	-	N/A	-	No 8/
164-3 - Forestry	TEP	-	N/A	-	No 11/
164-4 - Combination and Tank Mixes	-	-	N/A	-	No 12/
164-5 - Soil, Long-term	TEP	-	No	-	No 13/
Accumulation Studies					
165-1 - Rotational Crops	PAIRA	-	No	-	No 14/
165-2 - Rotational Cropps (Field)	TEP	-	No	-	No 14/
165-3 - Irrigated Crops	TEP	-	No	-	No 15/
165-4 - In Fish	TGAI or PAIRA	A	Yes	00077656*	No
165-5 - In Aquatic Non-Target Organisms	TEP	-	N/A	-	No 8/

Data submitted by Nor-Am Agricultural Products, Inc. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

§158.130 Environmental Fate
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radio labeled; TEP = Typical end-use product.

2/ The use pattern is coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic; Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted no later than September, 1986.

4/ A study is required to be conducted with controlled pH and temperature and using bacteria-free water.

5/ A study is required using soil TLC plates, not silica gel plates.

6/ Waived because this pesticide is a non volatile compound.

7/ Aerobic studies are required that identify metabolites and that are conducted on soils that are representative of soils upon which the pesticide is applied.

8/ There are no registered aquatic impact uses.

9/ A study is required that uses a sufficient amount of water for leaching.

10/ A new study is required because the metabolites were not identified and the sampling for parent and degradates was not conducted to the leaching depth.

11/ There are no registered forestry uses.

12/ This Guidance Document deals only with single active ingredients.

13/ Not required because there is more that 50% dissipation of this pesticide and its residues within 12 months after application to several test soils (see section 164-1).

14/ Waived because formetanate HCl dissipates rapidly in the field.

15/ Not required because formetanate HCl dissipates in the field and is not likely to be present in irrigation waters.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.135 Toxicology					
Acute Testing					
81-1 - Oral LD_{50}--Rat	TGAI	A	Yes	00077666	No
81-2 - Dermal LD_{50}	TGAI	A	Yes	00077666	No
81-3 - Inhalation LC_{50}--Rat	TGAI	A	Yes	00077668	No
81-7 - Acute Delayed Neurotoxicity--Hen	TGAI	A	No	-	No[4]
Subchronic Testing					
82-1 - 90-Day Feeding--Rodent, Non-rodent	TGAI	A	No	-	Yes
82-2 - 21-Day Dermal	TGAI	A	No	-	No[5]
82-3 - 90-Day Dermal	TGAI	A	No	-	No[5]
82-4 - 90-Day Inhalation--Rat	TGAI	A	No	-	Yes
82-5 - 90-Day Neurotoxicity--Hen/Mammal	TGAI	A	No	-	No[4]

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisty This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.135 Toxicology (continued)					
Chronic Testing					
83-1 - Chronic Feeding-- 2 species: Rodent and Non-rodent	TGAI	A	No	-	Yes[6]
83-2 - Oncogenicity Study-- 2 species: Rat and Mouse preferred	TGAI	A	No	-	Yes
83-3 - Teratogenicity-- 2 species	TGAI	A	No	-	Yes[6]
83-4 - Reproduction, 2-generation	TGAI	A	No	-	Yes[6]
Mutagenicity Testing					
84-2 - Gene Mutation	TGAI	A	No	-	Yes
84-2 - Chromosomal Aberration	TGAI	A	No	-	Yes
84-2 - Other Mechanisms of Mutagenicity	TGAI	A	No	-	Yes
Special Testing					
85-1 - General Metabolism	PAI or PAIRA	A	Yes	00077680*	No
85-2 - Domestic Animal Safety	Choice	A	Not Applicable	-	No[7]

* Data submitted by Nor-Am Agricultural Products, Inc.. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

§158.135 Toxicology (continued)

1/ Composition: TGAI - Technical grade of the active ingredient; PAI - Pure Active Ingredient; PAIRA - Pure Active Ingredient, Radio Labeled; Choice = on a case by case basis as to which composition is tested.

2/ The use pattern is coded as follows: A - Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor

3/ Data must be submitted no later than September, 1986.

4/ This study is not required because the chemical is not an organophosphate and it is not structurally related to a a substance that causes delayed neurotoxicity.

5/ Not required because the level of acute dermal toxicity is Category III.

6/ IBT studies submitted by the registrant pertaining to these tests have been found to be invalid. The Agency will determine if guidelines are met when replacement studies are furnished.

7/ Not required because there are no domestic animal uses.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirement	Composition 1/	Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A	No		Yes 4/
132-1 - Soil Dissipation	TEP	A	No		No 5/
133-3 - Dermal Exposure	TEP	A	No		Yes 6/
133-4 - Inhalation Exposure	TEP	A	No		No 7/

1/ Composition: TEP = Typical end-use product

2/ The use patterns are coded as follows: A - Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic, Outdoor; I = Indoor

3/ Data must be submitted no later than September, 1986.

4/ An interim reentry interval of 24 hours is required, or foliar dissipation data must be submitted to establish a decline curve.

5/ A field dissipation study is required. The results of that study should satisfy this requirement.

6/ An interim reentry interval of 24 hours is required or data on reentry exposure must be submitted. Registrants are advised to consult the Agency to ascertain whether acceptable surrogate data is available.

7/ This study is not required because the compound is non-volatile.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisty This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A	Yes	GS0091030* GS0091031*	No[12]
71-2 - Avian Dietary LC_{50}	TGAI	A	Partial	GS0091032*	Yes[4]
71-3 - Wild Mammal Toxicity	TGAI	A	Not Applicable	-	No
71-4 - Avian Reproduction	TGAI	A	No	-	Reserved[5]
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A	No	-	Reserved[6]
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A	Partial	00077658	Yes[7]
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A	No	-	Yes
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A	Partial	GS0091033*	Reserved[8]
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A	No	-	Reserved[9]
72-5 - Fish Life-Cycle	TGAI	A	No	-	Reserved[10]
72-6 - Aquatic Organism Accumulation	TGAI, PAI or De-gration Product	A	Not Applicable	-	No
72-7 - Simulated or Actual Field Testing -- Aquatic Organisms	TEP	A	No	-	Reserved[11]

ata Submitted by Nor-Am Agricultural Products, Inc. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

§158.145 Wildlife and Aquatic Organisms
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;

2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.

3/ Data must be submitted no later than September, 1986.

4/ The test animals used were much older than the recommended age of 10 to 17 days. Therefore, new studies are needed.

5/ Reserved pending receipt and review of environmental fate data and acceptable avain dietary LC_{50} studies.

6/ Reserved pending the evaluation of an avian reproduction study.

7/ The cited study on warm water fish ran for only 72 hours. It must be repeated and run for 96 hours. A test on a cold water fish must be submitted.

8/ Reserved pending receipt and review of environmental data. If data are required to support the citrus use, a 96-hour LC_{50} study on a estuarine or marine fish and a 48-hour EC_{50} study for oyster embryolarvae or 96-hour EC_{50} shell deposition study must be submitted. The 96-hour LC_{50} study on grass shrimp is acceptable.

9/ Reserved pending receipt and review of environmental fate data and acceptable avian dietary LC_{50} studies.

10/ Reserved pending receipt and review of environmental fate data and a fish early life stage and aquatic invertebrate lifecycle study.

11/ Reserved pending the results of an fish early life stage and aquatic invertebrate life-cycle and fish life-cycle studies.

12/ Both references must be cited.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirements	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP	A	No		No[4]
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI	A	No		No[4]
122-1 - Vegetative Vigor	TGAI	A	No		No[4]
122-2 - Aquatic Plant Growth	TGAI	A	No		No[4]
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI	A	No		No[4]
123-1 - Vegetative Vigor	TGAI	A	No		No[4]
123-2 - Aquatic Plant Growth	TGAI	A	No		No[4]
TIER III					
124-1 - Terrestrial Field	TEP	A	No		No[4]
124-2 - Aquatic Field	TEP	A	No		No[4]

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product. EP = End-use product.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than _____.
4/ These requirements are generally waived unless it is believed there is a phytotoxicity problem.

TABLE A

GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

Data Requirement	Composition [1]	Use Patterns [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	A	Yes	00006652**	No
141-2 - Honey bee--toxicity of residues on foliage	TEP	A	Yes	00077760*	No
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	A	Yes	00077760*	No
141-4 - Honey bee subacute feeding study		A	Not Applicable		No[4]
141-5 - Field testing for pollinators	TEP	A	Not Applicable		No[4]
Aquatic Insects					
142-1 - Acute toxicity to aquatic insects		A			Reserved[5]
142-2 - Aquatic insect life-cycle study		A			Reserved[5]
142-3 - Simulated or actual field testing for aquatic insects		A			Reserved[5]
Predators and Parasites					
143-1 thru 143-3		A			Reserved[5]

* Data submitted by Nor-Am Agricultural Products, Inc. These data may be compensable.

** Data submittec by by Rhone-Poulenc, Inc. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR FORMETANATE HCl

§ 158.155 Non-Target Insects
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Reserved pending development of an acceptable test method. When established, this requirement will be imposed on a case-by-case basis.

4/ Study not required because this compound is relatively non-toxic to honey bees.

5/ Reserved pending a decision as to whether these studies should be established as requirements.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FORMETANATE HCl

Data Requirement	Composition[1]	Does EPA Have Data To Satisty This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry				
Product Identity				
61-1 - Identity of Ingredients	MP	Partial	GS0091006*	Yes[3]
61-2 - Statement of Composition	MP	Partial	GS0091006*	Yes[3]
61-3 - Discussion of Formation of Ingredients	MP	No	-	Yes
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	Partial	GS0091006*	Yes[3]
62-2 - Certification of Limits	MP	Partial	GS0091006*	Yes[4]
62-3 - Analytical Methods for Enforcement of Limits	MP	Yes	GS0091006*	No
Physical and Chemical Characteristics				
63-2 - Color	MP	Yes	GS0091005	No
63-3 - Physical State	MP	Yes	GS0091005	No
63-4 - Odor	MP	Yes	GS0091005	No
63-7 - Density, bulk density, or specific gravity	MP	No	-	Yes

* Data submitted by Nor-Am Agricultural Products, Inc. These data may be compensable.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FORMETANATE HCl

Data Requirement	Composition [1]	Does EPA Have Data To Satisty This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry (continued)				
63-12 pH	MP	No	-	No[5]
63-14 - Oxidizing or reducing action	MP	No	-	Yes
63-15 - Flammability	MP	Yes	GS0091005	No
63-16 - Expodability	MP	No	-	Yes
63-17 - Storage Stability	MP	Yes	GS0091005	No
63-18 - Viscosity	MP	No	-	No[5]
63-19 - Miscibility	MP	No	-	No[5]
63-20 - Corrosion Characteristics	MP	No	-	Yes
Other Requirements				
64- 1 - Submittal of Samples	MP	No	-	Reserved

1/ Composition: MP = Manufacturing use product.

2/ Data must be submitted no later than March, 1984.

3/ Updated information must be supplied on identity and quantity of impurities and inerts.

4/ Explanation required from registrant on how certified limits are maintained.

5/ Not applicable for a solid material.

6/ The Agency will require a product sample on a case-by-case basis.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FORMETANATE HCl

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Yes	00077666	No
81-2 - Dermal LD_{50}	MP	Yes	00077666	No
81-3 - Inhalation LC_{50} - Rat	MP	Yes	00077668	No
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00077666	No
81-5 - Primary Dermal Irritation	MP	Yes	00077666	No
81-6 - Dermal Sensitization	MP	Yes	00077728*	No

1/ Composition: MP = Manufacturing use product.

2/ Data must be submitted no later than _____ .

* Data submitted by Nor-Am Agricultural Products, Inc. These data may be compensable.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This chapter applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This chapter applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10], as indicated by the following paragraphs of this chapter of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

A. Label Contents

40 CFR §162.10 requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix IV-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." [40 CFR §162.10(l)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

[Product Manager]
Phone No. (703)_____
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

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GS0091021 Nor-Am Agricultural Products, Inc. (1972) Formetanate HCl in or on Raisins and Dried Prunes (Unpublished study received Mar 1, 1972 under 2F1238; CDL:RCB-117725)

GS0091022 Nor-Am Agricultural Products, Inc. (1970) Residues in Apples and Pears (Unpublished study received May 22, 1970 under 0F0989; CDL:RCB-116294)

GS0091030 Fletcher, D.; Jenkins, D.H.; Keplinger, M.L. (1971) Acute Oral Toxicity Study with Carzol in Mallard Ducks - Report No. J 260 (Unpublished study received on July 7, 1983 under 2139-99; Prepared by Industrial Bio-Test Laboratories, Inc. Submitted by Nor-Am Agricultural Products, Inc., Naperville, IL.; CDL:250683)

GS0091031 Fletcher, D; Jenkins, D.H.; Keplinger, M.L. (1971) Acute Oral Toxicity Study with Carzol in Bobwhite Quail - Report No. J259 (Unpublished study received on July 7, 1983 under 2139-99; Prepared by Industrial Bio-Test Laboratories, Inc. Submitted by Nor-Am Agricultural Products, Inc., Naperville, IL.; CDL:250684)

GS0091032 Jackson, G.L.; Fancher, O.E.; Calandra, J.C. (1967) Bird Wildlife Studies EP-332 HCl - Report No. J5354 (Unpublished study received on August 11, 1983 under 2139-99; Prepared by Industrial Bio-Test Labs, Inc. Submitted by Nor-Am Agricultural Products, Inc., Naperville, IL.; CDL:250995)

GS0091033 Rausina, G. (1975) Four Day Static Aquatic Toxicity Studies with Carzol in Grass Shrimp and Shore Crabs - Report No. 621-06936 (Unpublished study received on August 11, 1983 under 2139-99; Prepared by Industrial Bio-Test Labs, Inc. Submitted by NOR-AM Agricultural Products, Inc. CDL:250994)

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				

63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: Initiation of Reregistration Process for Pesticide Products Containing Formetanate Hydrochloride as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the

steps you must take to maintain registration for your product(s). Products not brought into compliance with the Guidance Document as supplemented by subsequent information from EPA about compliance with certain data support requirements will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.

2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.

3. Sets out time-frames for submission of required data.

4. Explains how to revise labeling for maufacturing use products. (As the Guidance Document explains, labeling is not required at this time.)

5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that <u>if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended</u>.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

Product Manager 12
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

Enclosure

ATTACHMENT A

PRODUCTS AFFECTED BY THIS
REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

Product Name	EPA Reg. No.
Carzol SP	2139-99
Formetanate Hydrochloride	2139-114

ATTACHMENT B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING
THE ACTIVE INGREDIENT

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient and type of formulation, such as Manufacturing-Use Product (MUP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).

EPA Reg. No.	Co. Name and Address	Active Ingredient	Formulation Type
2139-99	Nor-Am Agricultural Products, Inc. 350 West Shuman Blvd. Naperville, IL 60566	92%	WP
2139-114	-do-	92%	MUP